Canadian Embassy

Ambassade du Canada

501 Pennsylvania Ave., N.W.
Washington, D.C. 20001

April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0276

"Registration of Food Facilities"

The Government of Canada welcomes the opportunity to review and provide comments on the above-referenced notice of proposed rulemaking as published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the *Federal Register* of February 3, 2003.

We find the requirement for all non-U.S. based food facilities to identify a U.S. resident agent as a condition of import to be an unreasonable and unnecessary requirement. We believe that the United States would find such a measure to be unacceptable if imposed on U.S. exporters by other countries. Consequently we request the U.S. agent identification to be optional.

If you have any questions on the submission, please contact the undersigned at 202-682-7629.

Sincerely,

John Masswohl
Agriculture & Fisheries Counsellor
Canadian Embassy

Canadian Embassy

Ambassade du Canada

501 Pennsylvania Ave., N.W.
Washington, D.C. 20001

April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0278

"Prior Notice of Imported Food"

Please find attached comments of the Government of Canada on rules proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)* with respect to the referenced subject.

If you have any questions on the submission, please contact the undersigned at 202-682-7629.

Sincerely,

John Masswohl
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Comments of the Government of Canada on rules proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).*

Docket No. 02N-0278

Prior Notice of Imported Food

We welcome the opportunity to provide comments on the above-referenced notice of proposed rule-making as published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the *Federal Register* of February 3, 2003.

We support the objectives of the *Bioterrorism Act of 2002* and the objectives stated by the FDA in the proposed rule for "prior notice". The Government of Canada has also taken measures to counter bioterrorism. During Congressional consideration of the *Bioterrorism Act*, the Canadian Government expressed its support to Congress and noted the importance of the prior notice provisions to both the United States and Canada, given that the two countries enjoy the world's largest bilateral trading relationship. Accordingly, we advocated providing the Secretary of Health and Human Services with the necessary regulatory authority to implement the prior notice provisions in a flexible way to achieve the objectives of the provisions, while at the same time taking account of the particular circumstances of movements across the Canada-United States border and the highly integrated nature of the economies of the two countries. The final law provides FDA with such flexibility.

In implementing the prior notice provisions, we want the FDA to succeed in achieving its objectives to counter bioterrorism while at the same time, as stated in Section III of the proposed rule, meeting United States international trade obligations, including the World Trade Organization agreements and the North American Free Trade Agreement, for example, by not making the rule more trade restrictive than necessary to meet the objectives of the *Bioterrorism Act*. In order to be effective, the prior notice rule must take into account the particular commercial environment at the Canada-United States border, which include large volumes of just-in-time deliveries and perishable food products.

General Comments

From our consultations with Canadian stakeholders, it is clear that the proposed rule is not flexible enough to avoid unnecessary disruption and disadvantage to Canadian exports of food products to the United States. In particular, the approach to the minimum time for advance notice and the limitations on who can submit the prior notice will impose unnecessarily rigid and, and some cases, impossible to meet conditions. The prior notice requirements should also reflect the relative low risks associated with imports of Canadian products, the modes of transport and shorter distances associated with imports from Canada and the large numbers of companies located at or very near the Canada-United States border.

We would therefore urge FDA to reconsider elements of its proposal. As stated, we fully support its purpose. However, these objectives must be achieved in a way which specifically takes into account the unique circumstances of the Canada-United States border. In this connection, we note that Section 302 of the *Act* includes a direction to the FDA to facilitate the importation of food in compliance with the requirements.

The *Act* gives the FDA fairly wide latitude to establish prior notice requirements that fit the circumstances applicable to various situations.

> "In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration."

The FDA should make full use of the discretion consistent with the other objectives of the statute. We note that the Secretary is not limited to the stated examples of factors which may be considered.

The FDA should take a risk-based approach. For example, the proposal does not take into account the Smart Border Plan agreed to and directed by Department of Homeland Security Secretary Ridge and Deputy Prime Minister Manley. A key element is the Free and Secure Trade (FAST) bilateral arrangements. Under the U.S. Customs-Trade Partnership Against Terrorism (C-TPAT) and the Canadian Partners in Protection (PIP) programs, companies approved by both countries have invested in specific counter-terrorism and supply chain integrity measures and are therefore accorded more expedited treatment at the Canada-United States border in recognition of the lower risk they present.

In December 2002, Department of Homeland Security Secretary Ridge and Deputy Prime Minister Manley announced that Canada and the United States have also agreed to cooperate on biosecurity under the Smart Border Plan. Regulatory agencies in Canada and the United States already cooperate on a unique and unprecedented basis. Under the Smart Border Plan and the bilateral cooperative initiatives on biosecurity, this cooperation will be enhanced, including in the area of food safety and countering

bioterrorism.

The FDA should build on and take advantage of these successful initiatives which share the FDA's counter-bioterrorism objectives and also reduce the risk for FDA's purposes. The FDA needs to determine how to provide special and less stringent treatment for low risk companies, such as those operating under FAST programs. This would allow FDA to focus its resources on sources of higher risk.

The FDA should ensure that maximum effort is made to work closely with the Bureau of Customs and Border Protection, Department of Homeland Security which is also developing prior notice requirements. It is critical that the two sets of requirements be consistent. Different and complex rules applied to the same commodities in pursuit of similar counter-terrorism objectives could introduce unnecessary costs for FDA, Canadian exporters and U.S. importers and consumers, and could create confusion, producing unintended obstacles to compliance.

Our specific comments below take into account the views received from many Canadian stakeholders regarding the proposals as published. We would intend to supplement our views should other feasible alternatives emerge as Canadian stakeholders and governments continue to review the serious questions involved in this proposed rule. In addition, we understand that many Canadian stakeholders are providing comments to the FDA directly and we would urge the FDA to give serious consideration to all of these comments. Of necessity, our comments are not exhaustive of all these views.

When Must the Prior Notice Be Submitted to FDA?

The proposed rule, in Section 1.286, requires the notice to be submitted to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing point. The prior notice can only be amended for limited product identity and quantity amendments and cannot be submitted until such time that all of the extensive required information exists. This proposal is premised both on the FDA's need to have adequate time to review prior notices and to dispatch inspectors to interdict suspect shipments.

This "one size fits all" approach is highly unlikely to work with respect to imports from Canada. It does not take account of the very short time between receiving an order, loading the order for transport and its delivery which is critical for many Canadian exporters, including exporters of perishable products and "just in time" deliveries. The proposed rule would preclude such transactions as well as any same day delivery and many next day deliveries. The problem is exacerbated by the fact that large numbers of Canadian exporters are located at or very near U.S. ports of entry (e.g. 30 minutes or less). For example, a Canadian company receiving an order shortly after 12 o'clock noon will have to ensure that the shipment does not arrive at the border until after midnight the next day i.e. 36 hours. Although we recognize that FDA has attempted to address these types of transactions, the ability to make an amendment to product identity and quantity will not relieve this situation.

We urge the FDA to reconsider this part of the rule and examine the following alternative approaches.

The minimum time period should be designed to align with the mode of transport. The statute provides this discretion and could be interpreted to encourage it. The statute also directs consultations with the Secretary of the Treasury (presumably now the Secretary of Homeland Security as well). Prior notice proposals with similar objectives being developed concurrently by the Bureau of Customs and Border Protection, Department of Homeland Security distinguish between modes of transport.

The FDA could establish a minimum time for vessels that reflects this mode of transport and that could be generally consistent with the requirement recently implemented by the Bureau of Customs and Border Protection. Notice is provided 24 hours in advance of the lading of a vessel. The FDA could benefit from this longer notice for vessels and could restrict or "cap" it to a maximum time of five days prior to arrival to reflect the FDA's statutory maximum. Imports by vessels from offshore will generally include imports of higher risk than imports of Canadian products.

For imports by truck, rail or aircraft, the FDA should establish times that reflect these modes and the commercial transactions involved, in particular at the Canada-United States border. It is important for the Canada-United States border that the minimum time allowed for notice strikes the right balance between the FDA's needs and the commercial environment of huge volumes shipped by truck and rail. For example, 45,000 trucks per day cross the border from the Province of Ontario alone. It is also important that the requirements of the FDA and the Bureau of Customs and Border Protection be as consistent as possible to avoid costly duplications, unnecessary disruptions and challenges to industry compliance.

The alternatives below regarding time of notice are premised on providing the same treatment of imports by truck, rail and air. As with trucks, shipments by air from Canada and shipments by rail from locations near the border will include the same quick turnaround between order and arrival at a port of entry. In its final analysis, if the FDA develops reasons why the same treatment for these modes may not be appropriate (i.e. different times for different modes), we strongly urge that the time established for each mode be designed carefully taking into individual circumstances.

In order to achieve its objectives and avoid any unnecessary adverse effects on imports from Canada, we recommend that the FDA provide options that are geared, in a general way, to actual business practices. FDA could require exporters to make an election and designate all or a part of their exports of food products according to the election.

The options below would incorporate a more flexible ability to amend and update notices. This ability is critical to quick turnaround business practices, in particular at locations at or very near ports of entry. These are covered under our comments on amendments and updates.

Option 1: Exporters whose business practices for all or a designated part of their products generally align (with or without some restructuring) with the current proposal of

noon the day before arrival (with the ability to submit limited amendments up to two hours before arrival) could elect to comply with the FDA's existing proposal for the time of prior notice. This may allow a wide variety of exporters to comply with accurate and full data and at the same time allow FDA a minimum of twelve hours (and in many cases much more) advance notice.

We would also ask the FDA to consider the merits of a variant i.e. a "rolling" or fixed advance number of hours. Rather than a rigid "noon the day before" formula, the FDA could require, for example, a fixed eight hour advance notice. This would provide much needed flexibility and would allow FDA a full work day for analysis provided that FDA staffed accordingly.

Option 2: Exporters that generally service quick turnaround orders for all or a portion of their products (e.g. same day orders, perishable products, "catch of the day", "just-in-time" deliveries) could elect to notify under this option (and restructure commercial practices, if necessary) to ensure that all the required information is available and notified no later than four hours before arrival. Under this option, minimal or no amendments would be permitted. This approach would better serve these types of transactions and provide accurate and full information to FDA earlier than the two hours provided for amended notices in the FDA's existing proposal. This would enable Canadian exporters to comply with FDA's need for accurate information enough in advance to interdict perceived risks.

In considering this approach, the FDA should consider that the majority of these types of transactions will daily, repetitive shipments of low risk products from Canadian companies well known to FDA border officials.

This four hour option is derived from FDA's analysis. A four hour advance notice appears to have been rejected, in part, due to the significant occurrence and cost to companies of dealing with inadequate notices in circumstances where the full information does not exist until less than 4 hours before arrival. It would appear that the proposal for noon the day before plus the ability to make limited amendment until up to 2 hours before arrival was developed as a solution.

As well, it appears to derive from FDA's sampling of actual Customs entries. The proposed rule does not address how representative the sample of 64 entries is and does not state whether or to what extent entries for imports from Canada were included. If the FDA intends to use such a sample as a basis for establishing the minimum notice time, we strongly encourage FDA to draw a sample representative of the enormous volume of shipments by truck and train at the Canada-United States border that would more accurately reflect the nature of imports from Canada. It is these shipments that will be most affected by the proposed rules.

Companies that have the full information prior to four hours will be able to comply with this 4 hour option. In circumstances where the information only exists less than four hours before arrival, we believe more flexibility as outlined below for amendment and updates would greatly alleviate this difficulty and provide FDA adequate time to target based on risk.

Although it is difficult for us to comment on the FDA's capabilities, from a resource or organizational standpoint, for analysis of prior notices consistent with the objective of the statute, it is not clear that 4 hours advance notice needs to be the basis of the above option. For example, if a lesser time were to provide adequate time for analysis, taking into consideration factors such as risk, the repetitive nature of products/shipments, locations near ports of entry, the nature of the product, then FDA should consider a lesser time (e.g. three hours) for advance notice based on these factors for companies electing this option.

The above "two options" approach would be consistent with FDA's objectives and provide the needed commercial flexibility to Canadian exporters to ensure the highest level of compliance for FDA.

Amendments and Updates

The FDA should consider shortening the time before arrival permitted for amendments. Under the proposed rule, amendments can be made up to two hours before arrival. However, it is not clear why two hours would be required. Considering that, as proposed, amendments would be limited to refining the identification of the product and quantity, FDA should consider a shorter time, for example, a minimum one hour before arrival. Sound targetting decisions and responses should still be achievable.

More flexibility in providing updates is critical to industry compliance and to avoiding unnecessary disruptions. Updates as proposed appear to be more of an operational consideration than driven by risk. We would suggest several changes that are key for the circumstances involved with imports from Canada.

As noted in the sensitivity analysis which was conducted, the estimated cost of the proposed rule is most sensitive to the assumed fraction of prior notices that will need to be changed. It is our understanding that a volume of greater than 20% of the notifications of perishable product shipments will need to be amended due to quantity changes and not identity changes. This will increase costs and errors caused through increased amendments. It is understood that amendments to the quantity of product arriving will impact sample sizes, however, it should not be a factor in decisions on whether to interdict a shipment for bioterrorism-related reasons based on the prior notice.

We recommend that refinements to the actual quantity loaded be considered as an update rather than an amendment. While estimates can be provided in the advance notice, the actual quantity is often not known until the time of loading. As noted above, the time between loading and arrival at the border is very short for large numbers of exporters located at or near ports of entry. It is not clear how a more precise quantity well in advance would contribute to sound targetting decisions. Consequently, refinement of the quantity loaded should be permitted as an update anytime before or at the time of arrival at the port of entry. Exporters can provide timely and accurate information for all elements of the prior notice and address precise quantities at loading in cases when the precise quantity becomes known only at this time. This could

alleviate a significant compliance problem for large numbers of Canadian exporters.

FDA should treat bulk shipments differently. Exporters of bulk commodities have recommended that FDA consider an acceptable load tolerance +/- 10% with respect to actual quantity. If within this range, amendments or updates should not be required for quantity. This will reduce greatly an unmanageable number of anticipated amendments or updates.

Multiple updates of time of arrival and the port of entry should be permitted and the window proposed for updates should be widened. Carriers often need to alter planned routes or become delayed for any number of reasons (e.g. road closings/construction, accidents, severe weather, mechanical problems) and this affects the time of arrival at the border. In addition, where a choice of ports of entry exists within a major gateway, carriers experiencing major delays at one port may re-route to a less busy port of entry. FDA should allow this needed flexibility. Carriers should be allowed to make corrections at the border since truck drivers may not be able to communicate electronically or in advance of arrival with U.S. Customs brokers. A lack of flexibility for carriers would also potentially increase congestion at ports of entry, creating an additional challenge to port of entry security procedures.

FDA should staff designated ports of entry at the Canada-United States border on a 24/7 basis. At such designated ports, FDA should not need to require updates of arrival.

The anticipated time of arrival and port of entry may be known to the exporter for purposes of prior notice. However, it is the carrier that will know with more precision during the journey. For this reason, carriers should also be permitted to provide updates.

With respect to truck transport, there will be circumstances where a driver cannot contact a dispatcher (e.g. at 2:00 am) for purposes of providing an update on arrival. FDA should provide flexibility in the rule for these and perhaps similar circumstances where, for legitimate reasons, it is simply not possible to provide an update.

Who Can Submit the Notice

The proposed rule, under Section 1.285, would require the prior notice to be submitted by a purchaser or importer who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United states, acting on behalf of the U.S. purchaser or importer. With respect to the particular commercial environment at the Canada-United States border, this proposal will impede FDA from receiving the most accurate and timely information in prior notices and will cause serious adverse and unnecessary commercial consequences for Canadian exporters and their U.S. customers.

Most imports from Canada are sold on the basis of the Canadian exporter taking responsibility for the entire U.S. Customs and FDA transaction at the border. The

Canadian exporter is the actual owner of the product until delivered to the U.S. customer. The invoice price to the U.S. customer will normally be inclusive of all U.S. customs or other U.S. border agency charges. The Canadian exporter normally hires and pays a U.S. Customs broker to act as its agent at the border, including the payment of duties or fees, and including, for example, any redelivery to FDA and Customs of any food shipments found to be non-compliant upon sampling and testing by FDA. The Canadian exporter is the U.S. importer of record.

If only resident U.S. parties or their agents are permitted to submit the notice, the FDA will be creating obstacles to its objectives.

The resident U.S. customer will need to provide prior notice information in a third hand manner as obtained from the Canadian exporter. This will inevitably introduce errors. In transactions involving perishable products or just in time deliveries or transactions involving companies located near to each other across the border, it will be more difficult to comply with the minimum time for advance notice. It is the Canadian exporter that will know the soonest and with the highest degree of accuracy precisely what is being shipped.

In any case where the shipment may be the subject of an inadequate notice, it is the Canadian exporter that normally owns the products at the border that would be held or sent to a secure facility. However, under the proposal the FDA will be requiring the resident U.S. customer which does not have a financial interest in the product to bear responsibility for compliance or disposal of the product. The inclination of the U.S. customer may be to simply abandon the shipment and cease to do business with the Canadian exporter.

From an operational standpoint, FDA is requiring detailed and extensive information for the prior notice. The level of detail is generally consistent with the information normally submitted by U.S. Customs brokers acting as agents for importers of record. As noted above, it is the Canadian exporter that hires such a customs broker and provides this information to the broker acting as the exporter's legal agent. The proposed rule would result in this information continuing to be submitted by Canadian exporters and their U.S. Customs brokers for Customs Service purposes yet, at the same time, requiring for the same transaction the submission of essentially the same data by a resident U.S. party (hiring the same or different broker) solely to comply with the FDA prior notice requirement. This will inevitably introduce complications, delays and inaccuracies for the FDA.

From a commercial standpoint, if resident U.S. customers have to hire a U.S. customs broker, incur additional expenses for submitting the notice and incur liabilities for holding products at the border, solely for purposes of the proposed rule, then a distinct competitive disadvantage will be newly introduced for Canadian exporters.

The directive of Section 302 of the Bioterrorism Act would indicate therefore that the FDA should include Canadian food exporters, and their U.S. Customs brokers (or other U.S. resident agent) in the requirements for who would submit the notice. We note that Congress did not specify which parties must submit the notice. To our knowledge,

these circumstances are unique to the Canada-United States border and, if necessary, FDA should exercise the needed regulatory flexibility to provide specifically for these circumstances. The FDA will receive the most accurate information available and in the most timely way consistent with FDA's objectives.

Repetitive Shipments

The statute does not permit FDA to require more than five days advance notice. However, the FDA is free to provide an optional voluntary notice for recurring shipments. We urge the FDA to develop such an option which might provide, for example, for a monthly or quarterly advance notice. A recurring shipment could be defined and limited by certain conditions. For example, daily shipments of the same product to the same customer would fall in this category. This would avoid daily repetitive notices, would provide predictability for FDA and reduce costs for both FDA and Canadian exporters while supporting the objectives of the statute.

Information That Must be Submitted

For each prior notice, the FDA is proposing to require much more information than the law specifies and we urge FDA to rethink some of these. In particular, multiple notices will be needed for essentially the same product from the same exporter 365 days a year. The FDA level of detail should be as compatible as possible with the entry line level of detail required to be submitted to the U.S. Customs Service. For example, it not clear how requiring a notice for different sizes of containers for the same product will substantially aid the FDA in targetting shipments. Such a requirement is likely additional to Customs requirements and will add substantially to costs.

In addition, it is very important for the FDA to clearly define the circumstances under which updates or amendments or resubmissions of notices must be made due to changes in the nature of the shipment after a notice is submitted. Without precision, interpretations and decisions by individual border officials could create uncertainty and disruptions.

The FDA should also amend/clarify the provision defining country of origin for fish products. It defines the originating country for wild caught fish for purposes of originating in the United States as being harvested in the U.S., or by a U.S. flagged vessel or processed on a U.S. flagged vessel. Otherwise the originating country is the country in which the article of food is produced.

FDA should amend this provision to clearly define the country of origin as the country in which the fish were last processed. Fish is a globally traded raw material which Canadian processors often source from several countries to make a like product for export. Defining country of origin as proposed for fish will lead to inevitable and likely uncontrollable errors for prior notice purposes. From a risk perspective, the last point of processing before exportation to the United States would likely be the point of greatest risk and greatest interest to the FDA.

FDA could also consider creating an optional field in the prior notice to indicate participation in other FDA programs/information systems or other department's or countries' programs that may be useful to FDA when analysing the prior notices. For example, a field to indicate the Bureau of Custom and Border Protection C-TPAT registration number could be useful in making targetting decisions.

Outreach and Clarifying Application

We appreciate the efforts of FDA officials to inform affected parties and to fully consider all comments. With the creation of these new rules, extensive new information requirements and the creation of new electronic supporting systems, it will be even more important for FDA to continue these outreach efforts as implementation proceeds. It will be equally important for FDA to ensure that administrative systems are fully operational and maintained to avoid any need to revert to a paper system. Even temporary shut downs will result in unmanageable congestion at the Canada-United States border.

In addition, many questions are being received concerning the precise coverage of articles of food over which FDA has jurisdiction (or over which the U.S. Department has exclusive jurisdiction). Precise answers to these questions are crucial because the question determines whether a prior notice is required. We urge the FDA to issue precise official information, as soon as possible and, in any case, well in advance of implementation, with specific guidance and examples so that Canadian exporters can determine whether they will be affected. For example, the question of coverage for live food animals is not clear and could affect large numbers of Canadian exporters of live food animals. We urge the FDA to work closely with USDA officials, if necessary, to produce an agreed document for guidance.

Future Amendments

The ability to amend the rules quickly is critical. When implemented later this year, these new requirements, despite careful design, could have immediate and significant and unintended consequences for the FDA's operations, carriers, Canadian exporters, U.S. importers and consumers, and the smooth operation of the Canada-United States border in general. Lessons learned and better ways of achieving the objectives should be quickly incorporated into the rules.

As noted above, the Canada-United States Smart Border Plan and its FAST objectives is a unique bilateral instrument to combat terrorism and, at the same, expedite low risk shipments, allowing enforcement agencies to focus on higher risks. In December 2002, Department of Homeland Security Secretary Ridge and Deputy Prime Minister Manley announced that Canada and the United States had also agreed to cooperate on biosecurity under the Smart Border Plan. Regulatory agencies in Canada and the United States already cooperate on a unique and unprecedented basis. Under the Smart Border Plan, this cooperation will be enhanced, including in the area of food safety and countering bioterrorism.

We strongly urge FDA to build into the final rule, the capability to amend administratively the prior notice provisions in respect of imports from any country for which the FDA has reached an arrangement that would serve as the basis for having different (e.g., more efficient or effective) prior notice requirements. Such a provision would be important for the FDA to adjust procedures quickly and efficiently to reflect reductions in risks achieved through such arrangements. In addition, a provision like this would provide the FDA with the ability to respond quickly to any serious unanticipated problems that might develop after implementation.